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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM A. KNAUS
and
RICHARD D. MARKS

Appeal 2007-004016
Application 09/816,152
Technology Center 3600

Decided:[1] June 29, 2009

Before MURRIEL E. CRAWFORD, ANTON W. FETTING, and JOSEPH A. FISCHETTI, *Administrative Patent Judges.*

FISCHETTI, *Administrative Patent Judge.*

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

Appellants seek our review under 35 U.S.C. § 134 of the Examiner's final rejection of claims 1-59. We have jurisdiction under 35 U.S.C. § 6(b) (2002). An Oral Hearing was held on April 22, 2009.

SUMMARY OF DECISION

We AFFIRM.

THE INVENTION

Appellants claim a system and method for individualized control and management of medical records. In particular, the invention relates to methods in which the creation, control, and management of medical records are secure and certified as accurate, having the attribute of non-repudiation. (Specification 1:8-10.)

Claim 1, reproduced below, is representative of the subject matter on appeal.

> 1. A broad-band, computer-based networked system comprising:
>
> a collection of patient-based electronic medical records containing medical information of a plurality of persons, wherein:
>
> the medical records are obtained and electronically compiled from a plurality of sources;
>
> one or more medical records of the collection possess a characteristic of non-repudiation such that the medical information contained within said medical records is verified as accurate and correct;

> the medical record of a person is transmissible in whole or in part only to that person and others authorized by that person;
>
> each medical record can be supplemented with additional information; and
>
> additional medical records for additional persons may be added to the collection;
>
> a secure access for allowing each person to access only their own medical record; and
>
> at least another secure access for allowing said others authorized to access only that person's medical record.

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Shear	US 4,827,508	May 2, 1989
Ertel	US 5,307,262	Apr. 26, 1994
Joao	US 6,283,761 B1	Sep. 4, 2001
Malik	US 2001/0037219 A1	Nov. 1, 2001
Segal	US 2001/0041991 A1	Nov. 15, 2001

Dixie B. Baker, *PCASSO: A Model for Safe Use of the Internet in Healthcare*, J. of AHIMA, 33-36 (2000) (hereinafter "Baker").

The following rejections are before us for review.

The Examiner rejected claims 1-11, 17, 30, 34-47, 51-55, and 57-59 under 35 U.S.C. § 102(e) as being anticipated by Segal.

The Examiner rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Baker.

The Examiner rejected claims 13-15, 20-22, 25-29, 32-33, and 48-50 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Malik.

The Examiner rejected claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Shear.

The Examiner rejected claims 18-19 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Ertel.

The Examiner rejected claims 23-24 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Malik as applied to claim 20 above, and further in view of Ertel.

The Examiner rejected claim 56 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Joao.

The Examiner rejected claim 40 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejected claim 40 under 35 U.S.C. § 101 as directed to non-statutory subject matter.

ISSUES

Have Appellants shown that the Examiner erred in rejecting claims 1-59 on appeal as being unpatentable under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) using Segal on the grounds that a person with ordinary skill in the art would understand that Segal's disclosure that computerized records are inherently more accurate than paper-based records in conjunction with an image server performs quality assurance checks on the images to verify diagnostic quality before releasing same constitutes a characteristic of non-repudiation such that the medical information contained within the medical records is verified as accurate and correct?

Have Appellants shown that the Examiner erred in rejecting claims 10,11, 21, 22, 41-43 and 45 on appeal as being unpatentable under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) using Segal on the grounds that a person with ordinary skill in the art would understand that Segal's disclosure that "computerized records are more organized, accurate, and accessible in comparison to paper-based records…" and "…before forwarding the images, image server performs quality assurance checks on the images to verify diagnostic quality" constitutes certification?

Have Appellants shown the Knaus and Marks Declarations to be sufficient in character and weight as to establish reduction to practice prior to the effective dates of the Segal and Malik references?

FINDINGS OF FACT

We find the following facts by a preponderance of the evidence:

1. The Specification describes the limitation "non-repudiation" in terms of:

> [m]edical records that are verified as accurate attain the aspect of non-repudiation (i.e.[,] that the accuracy and correctness of the information is as good or better than exists at the source sites from which the records were obtained), and may for all purposes be relied upon. As such, non-repudiated records may therefore be primary for future treatment or diagnoses.

(Specification 17:14-18.)

2. The Specification describes "certification" as having three modes as set forth below as follows:

> [a.] Certification levels may refer to standards of verification such as, for example, "initial" being self-certification wherein the member certifies that

> the record is correct, "basic" whereby the system provider certifies that the record is complete for all information gathered, "enhanced" whereby the system provider certifies that the information is complete and correct, or comprehensive" whereby the system provider certifies that the information provides a complete, accurate and verifiable medical record. Subdivisions of each level such as, for example, grades may also be utilized (e.g.[,] Basic-1, -2, -3, etc.).

(Specification 15:22-29.)

> [b.] Alternatively, the certification level may also provide an indication of the level of completeness of the record. For example, an initial level of certification may be limited to annual medical examinations. Data associated with such an examination is input into the system and each input would include an indication of source which may be verified by the system provider according to provider-defined criteria. A basic certification level may include information necessary for a initial certification level, plus additional information relating to hospital out-patient procedures performed along with source and source verification. An enhanced level of certification may include basic information plus further in-patient information. A comprehensive level may include enhanced information plus correlation information such as, for example, a review for completeness, vetting, a review for accuracy, and noting and/or linking of any discrepancies (e.g.[,] drug allergies, disparate diagnoses, anomalies, and otherwise unexplained treatments and observations).

(Specification 15:29-16:12.)

> [c.] Certification may simply state that the record is correct in all material respects or that the record

> is internally consistent. Errors identified in medical records may be corrected (with appropriate annotation) or simply noted. Suggestions in the form of supplemental computerized evaluations or other helpful comments may be included with comprehensive certification as to possible diagnoses, possible treatment or health options, and the like. Thus, a part of each level of certification may be a verification that the information is exactly as it appears in the paper or other tangible or even electronic file of the original source, or possibly better.

(Specification 16:12-19.)

3. The Specification defines patient–based as "… the medical records of an individual are controlled and managed by that individual.…" (Specification 13:4-6.)

4. The Specification describes vetting in the context of

> [f]urther information can be obtained from other sources (medical professionals and paraprofessionals, nurses, physicians), and all of the information subject to review and appraisal by clinically trained experts or record-experienced experts. Medical records that have been so reviewed are considered to have been vetted. Vetted medical records contain corrections and annotation information such as, for example, a review for accuracy and completeness noting and/or linking any errors or discrepancies (e.g.[,] drug allergies, disparate diagnoses, anomalies, and otherwise unexplained treatments and observations). Vetting may be a part of a certification standard (e.g.[,] comprehensive) or may simply be a statement that the record has been vetted and is correct in all material respects, is internally consistent and/or has been corrected.

(Specification 20:17-26.)

5. The Examiner found that Segal discloses "one or more medical records of the collection possess a characteristic of non-repudiation such that the medical information contained within said medical records is verified as accurate and correct (para. 6, para. 8, and para. 131 of Segal)." (Answer 6.)

6. The Examiner found that "Segal does not disclose wherein said collection complies with a federal or state standard of privacy and security, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996…" but that "Malik discloses wherein said collection complies with a federal or state standard of privacy and security, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996…" (Answer 14).

7. Segal discloses

> Electronic medical records (EMRs) digitally store the information found in traditional paper-based records. Other terms synonymous with EMR are computerized medical records (CMRs) and computer-based patient records (CPRs). As used herein, the term "patient medical record" (PMR) covers these electronic records (EMR, CMR, and CPR) as well as paper-based records. Inherently, these computerized records are more organized, accurate, and accessible in comparison to paper-based records. In addition, the computerized records have the potential to accommodate a greater variety of record media, such as medical imaging and videography.

(Segal, ¶[0008].)

8. Segal discloses:

> Image workstation 604 then forwards the digitized images and report, if generated, through an image center NAD 710 and an operations center NAD

> 702 to image server 126. Image server 126 then sends the images and report, if generated, for long term storage to expanded memory image archive 105 through NAD 702. Preferably, before forwarding the images, image server 126 performs quality assurance checks on the images to verify diagnostic quality.

(Segal, ¶[0131].)

9. The Knaus and Marks Declarations Exhibit A discusses the involved system and method in the future tense stating, e.g.: "PatientDirect will take advantage . . . " (p. 1¶B); "We will also expect to be involved in efforts to create an Extensible Markup Language. . . " (p. 4,¶C); "This illustrates the type and function of decision support tools possible for implementation in PatientDirect." (p.5, l. 2-3); "PatientDirect will collect and compile data from various locations of an individual's existing medical records . . . . " (p. 10, ¶B); "PatientDirect will strengthen. . . ," (p. 11¶A); "Web Links- will also be established with other support services that are applicable to the individual patient." (p. 13, ll. 3-4); "There will be two types of transaction fees . . . . " (p. 20,¶B). (Knaus Declaration, Exh. A.)

10. The Knaus and Marks Declarations seek to antedate the effective dates of each of Segal, Malik, the Segal Provisional, and the Malik Provisional applications relied on by the Examiner alleging *inter alia*:

> Prior to February 9, 2000, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in U.S. Patent Application No. 09/838,878 (Segal), U.S. Provisional Application No. 60/181,215 (the Segal Provisional), U.S. Patent Application No. 09/776,673 (Malik), and U.S. Provisional

> Application No. 60/60/200,091 (the Malik Provisional) (collectively the "Cited References"), as disclosed in the attached documents. Sections of the attached documents are highlighted to emphasize aspects of the instant invention that were alleged to be disclosed in these Cited References. Accordingly, Segal, Malik, the Segal Provisional and the Malik Provisional cannot be considered to be prior art to our claimed invention.

(Knaus and Marks Declarations, pp. 1-2.)

11. The Knaus Declaration does not assert any facts which show diligence.

PRINCIPLES OF LAW

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.")

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior

art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987).

ANALYSIS

Appellants' arguments against each of the rejections on the merits are based on perceived deficiencies of Segal. Inasmuch, as Appellants raise the same issues with respect to each of the rejections, we discuss them together, addressing each of Appellants' arguments in turn.

Preliminarily, we address the scope of the claims. Each of claims 1, 8, 9, 25, 26, and 54 requires *non-repudiation*, and each of claims 10, 11, 21, 22, 41-43, and 45 require *certification*. We rely on the Specification for the meaning of these terms in our analysis. According to the Specification, non-repudiation means that the accuracy and correctness of the information is as good or better than exists at the source sites from which the records were obtained (FF 5). Certify/certification means that the record is correct in all material respects or that the record is internally consistent (FF 6c).

Appellants argue that Segal fails to disclose nonrepudiation because "[i]n a preferred embodiment (e.g., claims 23, 24, 31), nonrepudiation is attained from an accurate medical record that is then subjected to a separate additional step of verification or vetting (*also see* specification, page 17, lines 11-21)." (Appeal Br. 11.) We disagree with Appellants. The involved claim language recites: "*one or more medical records of the collection possess a characteristic of non-repudiation such that the medical information contained within said medical records is verified as accurate and correct*." (Emphasis added.) Nowhere in this language is there a requirement of a two step process such as argued by Appellants whereby a

determined accurate medical record is subsequently subjected to a separate additional step of verification or vetting. All the claim language requires is that a record possess a characteristic of non-repudiation which is *medical information contained within said medical records is verified as accurate and correct*. This is not the same as the two step process which Appellants assert.

Appellants also assert that the language "*each medical record is certified as accurate*" (emphasis added) contained in each of claims 10, 11, 21, 22, 41-43 and 45 is not found in or made obvious by Segal. (Appeal Br. 11.) The Examiner however found the Segal at ¶¶ [0008] and [0131] discloses "one or more medical records of the collection possess a characteristic of non-repudiation such that the medical information contained within said medical records is verified as accurate and correct (FF 5). In these sections, Segal discloses "[i]nherently, these computerized records are more organized, accurate, and accessible in comparison to paper-based records…" and "…before forwarding the images, image server 126 performs quality assurance checks on the images to verify diagnostic quality…." (FF 7, 8.) We thus disagree with Appellants and agree with the Examiner's finding that Segal discloses record certification. As found *supra*, certification means that the record is correct in all material respects or that the record is internally consistent. (FF 2.) A computerized record which has undergone a quality assurance not only has the inherent accuracy of its nature, but Segal further discloses that the record is affirmatively checked for quality, e.g., accuracy. In light of the breadth of the claim, the Appellants' argument is not persuasive as to error in the rejection.

Declaration Evidence:

Claims 1-59

We are not persuaded by Appellants' showing of facts in the Knaus and Marks Declarations to be sufficient in character and weight as to establish reduction to practice prior to the effective dates of the Segal and Malik references. Rather, we find that the evidence presented in Exhibit A appended to the Declarations does not establish conception in that it discusses the concept only broadly and in the future tense (FF 9). Moreover, the Knaus and Marks Declarations Exhibit A fail to assert any facts of due diligence from the alleged time of conception date (FF 11), and thus cannot support conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application even if conception was established.

Accordingly, we reject Appellants' assertion (FF 10) that the Knaus and Marks Declarations are effective to antedate the effective dates of the Segal and Malik references and the rejections which rely on these references.

Claim 37

Claim 37 requires that the medical information contained within the medical records be more accurate and correct as compared to those sources from which the medical records were obtained. Appellants assert that this feature is not found "in any of the cited references relating to claim 37…." (Appeal Br. 7.) We disagree with Appellants because we read the source in Segal as the paper based record which when scanned or electronically copied, is expressly disclosed by Segal as being more accurate than the

paper based records. (FF 7.) In light of the breadth of the claim, the Appellants' argument is not persuasive as to error in the rejection.

Malik

Appellants argue that "Malik fails to disclose or suggest at least the elements of 'certification of medical records' (claims 21 and 22) or 'nonrepudiation of medical records' (claims 25 and 26) as these elements are claimed by Appellant." (Appeal Br. 17.) That argument is not well taken because the Appellants are attacking the reference individually when the rejection is based on a combination of references to both Segal and Malik, and Malik is only used to supplant the HIPPA requirement deficiency (Answer, 14). *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981); *In re Young*, 403 F.2d 754, 757-58 (CCPA 1968).

Claim 40

The Examiner rejected claim 40 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Appellants do not respond to this rejection in their Brief, and thus the rejection is deemed conceded.

The Examiner rejected claim 40 under 35 U.S.C. § 101 as directed to non-statutory subject matter. Appellants do not respond to this rejection in their Brief, and thus the rejection is deemed conceded.

CONCLUSIONS OF LAW

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 1-11, 17, 30, 34-47, 51-55, and 57-59 under 35 U.S.C. § 102(e) as being anticipated by Segal.

We conclude the Appellants have not shown that the Examiner erred in rejecting claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Baker.

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 13-15, 20-22, 25-29, 32-33, and 48-50 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Malik.

We conclude the Appellants have not shown that the Examiner erred in rejecting claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Shear.

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 18-19 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Ertel.

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 23-24 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Malik and further in view of Ertel.

We conclude the Appellants have not shown that the Examiner erred in rejecting claim 56 under 35 U.S.C. § 103(a) as being unpatentable over Segal in view of Joao.

We conclude the Appellants have not shown that the Examiner erred in rejecting claim 40 under 35 U.S.C. § 112, second paragraph.

We conclude the Appellants have not shown that the Examiner erred in rejecting claim 40 under 35 U.S.C. § 101 as directed to non-statutory subject matter.

DECISION

The decision of the Examiner to reject claims 1-59 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED

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